K053425

poc inc.

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SECTION VII

510(k) SUMMARY

Submitter's Name & Address:	Precision Optics Corporation, Inc. 22 East Broadway Gardner, MA 01440
Contact Person: **Telephone:** **Telefax:**	Erwin E. Heider 978-630-1800 x 155 978-630-1487
Date Summary Prepared:	July 29, 2005
Device Name:	Classification Name – Direct and Indirect Ophthalmoscope Common / Usual Name – Video Ophthalmoscope Model Number – 2500-VOS
C.F.R. Section:	886.1570
Product Code:	HLJ
Device Class:	II
Classification Panel:	Ophthalmic (Battery Powered)
Predicate Device:	Welch Allyn Video Ophthalmoscope (510(k) #K951210)

Device Description:
The Precision Optics Corporation Video Ophthalmoscope is a hand held indirect and direct monocular device for use by trained personnel for viewing / examining the cornea, aqueous, lens, vitreous, and retina of the patient's eye(s). The viewing path is split in two via a beamsplitter to provide for direct viewing by the trained personnel as well as simultaneous video imaging on a monitor either near or at the patient or at a remote site via telemedicine techniques. The viewing system is comprised of objective lenses, relays, a beamsplitter, and eyepiece and provides an erect, un-reversed image of the patient's retina to the trained personnel.

Intended Use:
This ophthalmoscope is intended to be used by trained personnel to examine the cornea, aqueous, lens, vitreous, and retina of the eye.

Technological Characteristics & Comparison to Predicate Device:
The Precision Optics Corporation video ophthalmoscope is very similar in design and performance to the Welch Allyn video ophthalmoscope (510(k) #K951210). The design and construction of the beamsplitter portion as well as most technical parameters are identical. Minor differences exist in the illumination controls, number of apertures, number of filters, specific diopter settings and shape of handle, but these differences are not critical to performance

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in general use. The Maximum Device Temperatures of the Welch Allyn video ophthalmoscope were not known, but those measured for the Precision Optics video ophthalmoscope were all below 33 °C. Also, tests performed to determine electrical and optical radiation safety of the Welch Allyn video ophthalmoscope were unknown. The Precision Optics Corporation video ophthalmoscope complies with international standards for electrical safety (IEC 60601-1) and optical radiation (ISO 10942 and ISO 10943 – Section 5.5).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Precision Optics Corporation
c/o Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Services NA, Inc.
70 Codman Hill Rd.
Boxborough, MA 01719

Re: K053425
Trade/Device Name: Precision Optics Corporation Video Ophthalmoscope, Model 2500-VOS
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLJ
Dated: December 28, 2005
Received: December 29, 2005

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

POC inc.

SECTION III

Indications for Use

510(k) Number (if known): K053425

Device Name: **Precision Optics Corporation Video Ophthalmoscope (2500-VOS)**

Indications For Use: **The Video Ophthalmoscope is intended to be used by trained personnel to examine the cornea, aqueous, lens, vitreous, and retina of the eye.**

Prescription Use ___X___ AND/OR Over-The-Counter Use _N/A__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OBE)

Gwendolyn P. Cowan

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K053425